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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/076,956 06/13/98 BARANOVA

L P60188USA

EXAMINER

HM22/0307

CRANE, L

ART UNIT

PAPER NUMBER

1623

DATE MAILED:

03/07/00

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary	Application No. 09/076,954	Applicant(s) Baranova et al.
	Examiner L. E. Crane	Group Art Unit 1623

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

Responsive to communication(s) filed on 02/22/00 (CPA) =-----

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

Claim(s) 80-103 ----- is/are pending in the application.

Of the above claim(s) ----- is/are withdrawn from consideration.

Claim(s) ----- is/are allowed.

Claim(s) 80-103 ----- is/are rejected.

Claim(s) ----- is/are objected to.

Claim(s) ----- are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on _____ is approved disapproved.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Reference(s) Cited, PTO-892

Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948

Other _____

Office Action Summary

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The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 1600, Art Unit 1623.

5 Claims 18-31 have been cancelled and new claims 32-47 were entered as per the amendment filed February 5, 1999. A revocation and substitution of power of attorney was entered June 1, 1999 and notification of acceptance was mailed June 15, 1999. Subsequently, claims 32-47 were cancelled and claims 48-79 were entered as per the amendment of June 25, 1999. And lastly claims 48-79 were cancelled and new claims 80-103 were entered as per the amendment originally filed after final and entered March 2, 2000 as per the request accompanying the CPA request filed February 22, 2000.

15 Claims 80-103 remain in the case.

Claims 80-103 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

20 In claims 80-81, 90-91 and 97-100, line 2, the term "comprising" is incorrect in the instant claim because said term implies that the chemical structure of the compound being claimed contains additional structural component(s) not defined in the claim, i.e. implies that the metes and bounds are indefinite. Applicant is respectfully requested to substitute narrow language such as --

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consisting of -- or the like for the noted term. A similar problem reoccurs in claims **83** at line 1 ("comprises").

5 In claims **80–81, 90–91 and 97–100**, line 3, the variables "C₁" and "C₂" are not defined (carbon atoms?) and the attached semicircular line in claims **80–81 and 97–98** is also not defined, thereby rendering the instant claims incomplete.

In claims **80–81 and 90–91**, line 4, the term "protecting group" lacks an upper bound thereby rendering the instant claim indefinite.

10 In claim **80**, lines 7–8, the definition of variables "R₁" and "R₂" is completely functional and includes improper process limitations ("is inert under conditions of polynucleotide synthesis") and therefore is lacking in the adequate guidance required by the ordinary practitioner to determine which functional groups are properly included, and which functional groups are not properly included, 15 within the metes and bounds of the instant claim. This rejection also applies to variable "R'₂" in claims **91 and 100**, and to variable "R'₁" in claim **99**.

20 In claim **80–81**, line 6, the term "W is acyl" is lacking an upper bound thereby rendering the instant claim indefinite. The same problem reoccurs in claims **90–91 and 97–100**.

25 In claim **80–81**, line 9, the term "X is an organic spacer group" is lacking an upper bound thereby rendering the instant claim indefinite. The same problem reoccurs in claims **90–91 and 97–100**.

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In claims **80–81**, line 10, the term “P is an organic or inorganic polymer” is technically incorrect and/or incomplete, because any such polymer must be bound to the generic linking structure making the polymer chemically a substituent radical, not a compound as defined by the noted term. Applicant is respectfully requested to re-define the noted term and include therewith a more complete definition concerning the structure(s) of the linkage which chemically binds the polymer to the generic structures of claims **80–81** through the bonding at the location defined by variable P. The same problem reoccurs in claim(s) **90–91 and 97–100**.

Claims **82–83**, the term “heterocycle” is incomplete because the claims fails to include sufficient further definition of which atom or atoms of the hetero ring is/are a heteroatom(s), what is the intended upper limit of ring size, and only in claim **82**, which heteroatoms are intended. The same problem reoccurs in claim [].

In claims **82 and 84**, line 1, variables “C₁” and “C₂” lack proper antecedent basis because said variables while present in the chemical formula at line 3 of parent claim **80** were not further defined therein.

In claim **84**, line 2, the term “ribose ring” is incomplete for failure to specify all of the structural details of the “ribose ring” and the linkage(s) thereof to the other component parts of the claimed solid support. A similar problem reoccurs in claim [].

In claim **87**, line 3, the terms “alkyl” and “halogenated derivatives of alkyl” are lacking an upper bound thereby rendering the instant claim indefinite. The included term “derivatives” is also

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open ended which renders the instant claim indefinite because the metes and bounds of said term are also not adequately defined. The same problem reoccurs in claims **94 and 101**.

In claim **90**, line 3, the variable "R'1" is presented in the chemical structure but is not further defined anywhere within the remainder of the claim. Additionally, the variable "R'2" is apparently superfluous because while said term is defined at lines 7-8, it is not present anywhere within the structure at line 3.

In claims **90-91 and 99-100**, line 3, the generic structures are indefinite because the structural implications of moving variable substituents " R " and " X-P " from C₁ to C₂ or visa-versa is unclear. A similar problem in determining the actual location of variable " X-P " occurs in claims **80-81 and 97-98**. Applicant is encouraged to use complete organic structures in independent claims wherein these variations are either avoided or explained clearly.

In claims **97-100**, the introduction of the variable "M" is done in a manner which makes the length of the "nucleotide" attached thereto indefinite for lack of an upper bound.

Claims **80-103** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Independent claims **80-81, 90-91 and 97-100** are each drafted with functional limitations which imply a breadth of claim scope which encompasses exemplifications not enabled within the

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instant disclosure. Additionally, no single dependent claim provides a cure for this lack of enablement by limiting the scope of the claimed subject matter. For these reasons, all of the instant claims (80-103) are deemed to lack adequate supporting enablement within the instant disclosure because the number of specific embodiments presented is insufficient to adequately enable the scope of each instant claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

Claims 90-96 and 99-103 are rejected under 35 U.S.C. §102(a) as being anticipated by Lyttle et al. (PTO-892 ref S). (See also the US patent equivalent 5,688,940, PTO-892 ref. H).

The instant claims are directed to compounds which include an oligonucleotide cleavage capable nucleophilic function "Y" and its protected precursor "Y-W" which are deemed to read on one or more of the compounds numbered 1, 4 and 5 as disclosed in the Lyttle et al. reference at Fig. 1, col. 1, of p. 2795, and particularly to read on the first structure of Figure 2 at column 1 of page 2796.

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Claims **90–96 and 99–103** are rejected under 35 U.S.C. §102(b) as being anticipated by Nelson et al. (PTO-892 ref. Y).

Applicant is referred to p. 7188, Figure 1 wherein the structure labeled “MF-CPG” (final product) anticipates the instant noted claims **90–96**. The associated text at pp. 7187–7188 which teaches attachment of a growing nucleotide in place of the DMT group thereby anticipates instant claims **99–103**.

Claims **90–96 and 99–103** are rejected under 35 U.S.C. §102(b) as being anticipated by Vu et al. (PTO-892 ref. V).

Applicant is referred to p. 604, Figure 1, the compounds labeled with numbers **5, 6, 13, 19, 26 and 32**, each of which anticipate applicant's invention. Applicant will note with the abstract discussion to the effect that the phthalimido protecting group was inserted herein to prevent “spontaneous cleavage” of the oligonucleotides from the solid support.

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

“A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.”

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Claims 80-89, 97-98 and 101-103 are rejected under 35 U.S.C. §103(a) as being unpatentable over Lytle et al. (PTO-892 ref S). (See also the US patent equivalent 5,688,940, PTO-892 ref. H).

The instant claims are directed to the invention encompassed by 5 claims 90-96 and 99-103 with the only differences being the presence of a cyclic structural element, optionally a heterocyclic ring, and further optionally a ribosyl moiety incorporating "C₁" and "C₂" as 2'- and 3'-ribosyl ring carbons, respectively, and the presence of optional alternative protected hydroxyl, protected N-alkylamino, or 10 protected thio in place of protected amino as the protected reactive functional group "W-Y."

Lytle et al. reference at Fig. 1, col. 1, of p. 2795 discloses derivatized solid supports which read on the instant claimed 15 derivatized solid supports as noted supra. The instant reference does not include, i) N-alkyl analogues and ii) embodiments wherein the protected amino function and the solid support are connected by a moiety containing a cyclic structure which serves only a connecting function.

The disclosure in the prior art of a derivatized solid support 20 which contains all of the chemically necessary structural and reactive elements of the instant invention, but does not contain a ring-forming structural element which serves only a connecting function and does not optionally include a protected hydroxyl group, a 25 protected N-alkylated amino group or a protected thio group as the protected reactive group, is deemed to render the instant claimed derivatized solid support *prima facie* obvious in the absence of a showing of unexpected results associated with the presence of the

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cyclic connecting element and/or the alternative reactive functional groups.

Therefore, the instant claimed ring containing derivatized solid supports useful in oligonucleotide synthesis and solid support separation would have been obvious to one of ordinary skill in the art having the above cited references before him at the time the invention was made.

In view of the disclosure of Vu et al. concerning unanticipated cleavage of ODN's from the solid support, both the Vu and Nelson references are deemed to be equivalents of the Lyttle reference. Therefore, this paragraph is considered to be the equivalent of obviousness rejections citing the relevant portions of Vu and Nelson in place of Lyttle in the rejection supra.

References made of record but not cited above are deemed to be either equivalents to the cited references or to be of interest as closely related prior art which shows the state of the relevant prior art.

Note to applicant: The submission of a portion of the textbook authored by J. March is noted, but cannot be made of record because the date of publication has not been included within the instant submission. Applicant is encouraged to resubmit the reference and list author, title and pages submitted of same together with publisher, location and date of publication on a PTO-1449 so that same may be made of record.

Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such

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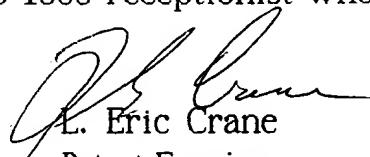
papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the FAX machines operated by Group 1600 are **(703) 308-4556** and **703-305-3592**.

5 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **703-308-4639**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

10 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Gary Geist, can be reached at (703)-308-1701.

15 Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **703-308-1235**.

LECrane:lec
03/03/00



L. Eric Crane
Patent Examiner
Group 1600